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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,212	01/04/2002	John Colyer	10069/1004	6487

29933 7590 06/15/2004

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,212

Applicant(s)

COLYER ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) 1-37,39,53-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,40-52 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Response to restriction requirement filed 03/25/2004 is acknowledged. Applicant elected, with traverse, Group III.1, claims 38-52,91. Insofar as applicants have not specifically pointed out the reasons supporting the statement of the traversal, applicants' election is taken to be without traverse. See MPEP 818.03(a). The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1-37, 53-90 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1-37, 53-90 is requested.

In regard to request to elect species of fluorescently labeled peptides, upon further consideration, examiner deems that various fluorescent labels are obvious variants, and, therefore, vacates the requirement.

Further restriction

Upon further consideration of the elected Group, the following additional restriction of was deemed necessary.

The elected group is drawn to method to monitor activity of an enzyme comprising addition of phosphate moiety. Contrary, however, claim 39 (and claims

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dependent thereupon) are drawn to monitoring activity of enzyme operating in reverse direction, namely removal of phosphate moiety. Consequently, the method is patentably distinct, as it requires different agents (not the non-phosphorylated peptide of claim 1), and have different mode of operation.

As applicant elected Group III.1, drawn to addition of phosphate moiety, this group is considered to be constructively elected. Claim 39 is withdrawn from consideration. Cancellation of claim 39 is requested.

Further, amendment of claims 40, 41, 91 to read on elected subject matter is requested.

Claims 38,40-52,91 are examined on merits to the extent they read on elected invention.

Information Disclosure Statement

Applicants' Information Disclosure Statement filed 06/24/2002 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Title, Abstract

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The title and abstract of the invention are not descriptive. The title and abstract do not reflect the elected invention. A new title and abstract are required which are clearly indicative of the invention to which the elected claims are directed.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38,40-52,91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

- A. Claim 38 recites reporter molecule described in non-elected claim. Please amend the claim to incorporate the subject matter of the claim withdrawn from consideration.
- B. Claims 40, 41, 91 recite subject matter drawn to non-elected claims. Amendment of claims 40, 41, 91 to read on elected subject matter is requested.
- C. Claims 38,40-52,91 use the term "binding partner" which is vague and indefinite. The specification, although providing particular examples, does not provide

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a standard for ascertaining the requisite composition, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

D. The term "polypeptide comprising a coiled-coil " used in the claims is a relative term which renders the claim indefinite. Coiled coil is a relative term describing spatial orientation rather than structure of the polypeptide. Besides the structural requirements, appearance of the coiled coil spatial orientation depends on a number of environmental factors in the medium, for example, on the presence or absence of certain co-factors. No standard of reference has been provided in the instant disclosure with which to determine whether a particular organ is "polypeptide comprising a coiled-coil " or not. Accordingly, it is not possible to determine what products are embraced within the scope of the claim.

D. Claims 41,43: Both claims lack antecedent basis as their respective base claims 38 and 42 do not recite "said mixing step" and "said fluorescence emitting means", respectively.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 41-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods wherein reporter moiety and its binding partner are the same and the binding is dimerization, does not reasonably provide enablement for any other "binding moiety". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a method to monitor the activity of an enzyme (kinase) comprising the step of monitoring the addition of a phosphate moiety wherein the method includes mixing an enzyme that adds the moiety that to reporter molecule and its binding partner and measuring the change in energy transfer between said reporter molecule and its binding partner.

The specification generally defines "binding partner" as a "polypeptide or fragment thereof (a peptide) that binds to (associates with) a polypeptide comprising a coiled-coil according to the invention. Except for a particular example where the binding partner is the same as "reporter molecule" and the binding process is dimerization (paragraphs #[0123], [0144],[0171]), alternative meanings of a "binding partner" are not disclosed, and no corresponding working examples are present.

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In view of the above, it is the Examiners position that with the insufficient guidance and working examples one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38, 40,45,49-52,91 are rejected under 35 U.S.C. 103(a) as obvious over Tsien et al (US Patent 6197928).

Tsien et al teach method for determining the concentration of an analyte in a sample using a fluorescently labeled peptide comprising a binding protein moiety having an analyte-binding domain which binds an analyte, a donor fluorescent protein moiety covalently coupled to the binding protein moiety, and an acceptor fluorescent protein moiety covalently coupled to the binding protein moiety, wherein analyte binding to the analyte binding domain causes a conformational change in the analyte binding domain which in turn induces conformational changes in the position or orientation of the donor fluorescent protein and acceptor fluorescent protein moieties with respect to one another, thereby altering the relative amounts of fluorescence from the two fluorescent protein moieties when the donor is excited by irradiation. See claim 24. The binding is measured by energy transfer, FRET using two fluorescent

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labels (claims 19,25-27) . In FRET, the "donor fluorescent protein moiety" and the "acceptor fluorescent protein moiety" are selected so that the donor and acceptor moieties exhibit fluorescence resonance energy transfer when the donor moiety is excited. The binding protein moiety can be a kinase (claim 11).

Although the referenced claims are not drawn to "monitoring activity of an enzyme", such as kinase, as instantly claimed, it would be *prima facie* obvious to one skilled in the art that, as a kinase is one of the possible binding proteins used in the method, the method can be used to monitor phosphorylating activity of a kinase (i.e., activity resulting in an attachment of a phosphate moiety).

In regard to "site sufficient for the addition of [phosphate] moiety", every protein actin contains a plurality of residues suitable for addition of a phosphate moiety (e.g., Ser, Thr, Tyr, His, and Lys residues).

In regard to term "engineered" the term refers to way of preparing the claimed compound rather than distinguishes it structurally from products obtained otherwise. It is the novelty and patentability of the instantly claimed product that need to be established and not that of the process of making steps.

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Claims 38,40,49,91 are rejected under 35 U.S.C. 102(b) as anticipated by Bastaenis et al.

The reference teaches monitoring activity of protein kinase C by monitoring interaction between labeled kinase (and hence monitoring of the addition of phosphate moiety) and fluorescently labeled antibody. Fluorescence resonance energy transfer (FRET) between the labeled cPKC and the antibody was used to detect proteolytic processing of the protein in situ in response to exposure of the cell to the protein kinase C activator, phorbol myristate acetate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

